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EXAMINER

JANSSEN, SHANNON L.

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Continued

The amendment filed August 5, 2011 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because of the following:

a. The proposed amendment requires further consideration and/or search (e.g. the new limitation “diagnostic assay” and “wherein the predetermined human mRNA profile is the mRNA profile from a human without known oropharyngeal squamous cell carcinoma (OSCC) and wherein a statistically significant increase in mRNA expression of the gene coding for ILS, DUSP 1, H3F3A, OAZ1, S 100P, IL 1 b or SAT in the mRNA profile relative to the predetermined human mRNA profile is indicative of OSCC” of claim 10 and new claims 29-33, which limitations are narrower in scope than the previously examined claims). In accordance with MPEP 803.02, should applicant overcome a rejection by amending a claim, the search concerning amended claims will need to be altered to the extent necessary to determine patentability.

b. The proposed amendment may necessitate the modification of outstanding rejection(s) to address the new limitation (e.g. the new limitation “diagnostic assay” and “wherein the predetermined human mRNA profile is the mRNA profile from a human without known oropharyngeal squamous cell carcinoma (OSCC) and wherein a statistically significant increase in mRNA expression of the gene coding for ILS, DUSP 1, H3F3A, OAZ1, S 100P, IL 1 b or SAT in the mRNA profile relative to the predetermined human mRNA profile is indicative of OSCC” of claim 10 and new claims 29-33, which limitations are narrower in scope than the previously examined claims).

c. The proposed amendment may necessitate the raising of new prior art rejections (e.g. the new limitation “diagnostic assay” and “wherein the predetermined human mRNA profile is the mRNA profile from a human without known oropharyngeal squamous cell carcinoma (OSCC) and wherein a statistically significant increase in mRNA expression of the gene coding for ILS, DUSP 1, H3F3A, OAZ1, S 100P, IL 1 b or SAT in the mRNA profile relative to the predetermined human mRNA profile is indicative of OSCC” of claim 10 and new claims 29-33, which limitations are narrower in scope than the previously examined claims).

d. The proposed amendment may necessitate the raising of new 112 issues (e.g. the new limitation “diagnostic assay” and “wherein the predetermined human mRNA profile is the mRNA profile from a human without known oropharyngeal squamous cell carcinoma (OSCC) and wherein a statistically significant increase in mRNA expression of the gene coding for ILS, DUSP 1, H3F3A, OAZ1, S 100P, IL 1 b or SAT in the mRNA profile relative to the predetermined human mRNA profile is indicative of OSCC” of claim 10 and new claims 29-33, which limitations are narrower in scope than the previously examined claims).

e. The proposed amendment presents additional claims without canceling a corresponding number of finally rejected claims and therefore it is not considered as placing the application in better condition for appeal. Ex parte Wirt, 1905 C.D. 247, 117 O.G. 599 (Comm'r Pat. 1905). The proposed amendment presents 5 additional claims and cancels 2 finally rejected claims.

f. There is no convincing evidence under 37 CFR 1.116(b) why the proposed amendment was not earlier presented.

g. Applicants arguments of the prior art of record are moot since the arguments are based on the proposed amendments that have not been entered (e.g.: for the amendment of claim 10 to be directed to a “diagnostic assay”). It is further noted that the examples provided by applicants regarding enablement (e.g., response, p 5) are not directed to a method of diagnosis, as currently claimed.

h. For all the reasons above, the amendment does not place the application in better condition for allowance and/or appeal.

Response to Arguments

Applicant's arguments filed August 5, 2011 have been fully considered but they are not persuasive for the following reasons. Applicants' arguments are presented in Italics.

Applicants assert that the detection of a biomarker in a cell does not indicate that the biomarker would be detectable in the extracellular milieu (Response, pp 6-7).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the biomarker is not intracellular) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Specifically, the instant claims recite a "saliva supernatant" which does not exclude supernatant from ruptured cells (e.g.: the instant claims do not recite a cell-free sample and a saliva sample containing HNSCC cells that were ruptured and subsequently spun down could be broadly and reasonably interpreted as a saliva supernatant and would contain intracellular materials).

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANNON JANSSEN whose telephone number is (571)270-1303. The examiner can normally be reached on Monday-Friday 10:00AM-7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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